

contain chemical formulas in describing the claimed compounds and not figures. If clearer copies are necessary, Applicants will provide them.

Rejection Under 35 USC §112, first paragraph

In making a non-enablement rejection under 35 USC §112, first paragraph, it is incumbent upon the PTO to present reasons to doubt the veracity of statements presented within the Applicants' specification. See e.g., *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971) and *Fiers v. Sugano*, 25 USPQ2d 1601, 1607 (Fed. Cir. 1993). The rejection fails to provide any evidence or rationale to support the assertion of non-enablement. Beginning near the bottom of page 31, the rejection asserts, "... the specification, while being enabling for R_x, R_z and R_f to be lower alkyl, does not reasonably provide enablement for any hetero or other large groups of 1-30 or 1-40 carbon atoms with other heteroatoms."

Applicants maintain this is an unsupported conclusion. The application provides general preparative methods on pages 12-16 to guide one skilled in the art to prepare the claimed compounds. Numerous references are also identified on page 12 for obtaining the desired starting materials. The specification also discloses how to prepare pharmaceutical agents with the compounds of the invention and how to administer them on pages 16-21 of the specification. Pages 25-61 provide greater detail in preparing certain starting materials and intermediates as well as procedures to use these materials to prepare the claimed compounds. On pages 62-85, the synthesis of over 100 compounds is provided. In view of this general and detailed description, the specification clearly provides an enabling disclosure for the subject matter claimed.

The observations made with regard to "the breadth of the claims, nature of the invention, state of the prior art, the level of one of ordinary skill, the level of predictability in the art and the quantity of experimentation needed to make or use the invention" do not support a finding of non-enablement, even if true. As to the "nature," "prior art" and "predictability" factors, the examiner has provided no reasons to doubt any encompassed compounds are useful as disclosed.

Moreover, it is noted that two of the eight factors identified in the office action as relevant to a determination of whether any necessary experimentation was undue were not mentioned. No reference was made indicating these factors were considered in the analysis of Applicants' specification for enablement. These factors are: 6) the amount of direction provided

by the inventor, 7) the existence of working examples. These factors are not insignificant and if properly considered, it is clear any necessary experimentation would not be undue.

It also alleged that there are working examples with respect to only one of the substituents "CONR_aR_b". However, the compounds of examples 2, 9, 10, 48, 53, 54, 55 have substituents other than CONR_aR_b. One skilled in the art can replace the aniline starting materials used to make these compounds with the anilines described in examples 104-108 without undue experimentation to prepare compounds claimed herein with a substituent other than CONR_aR_b. It is well settled law that the test for enablement is not whether any experimentation is needed but whether or not the experimentation is undue. *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976).

As to whether the specification enables compounds with R_z, R_x and R_f other than lower alkyl, it is also noted that the following examples illustrate compounds wherein R_y, R_z, R_x or R_f are other than lower alkyl: Examples 6, 7, 23, 26, 28, 31, 33, 34-40, 46, 54, 60-65, 68, 70, 71, 73-84, 94, and 112. When the direction provided by the Applicant through these examples is considered, the compounds where R_x, R_z and R_f are other than lower alkyl are clearly enabled. In any event, the nature of exemplification is in no way determinative of enablement.

In view of the above remarks, it is respectfully submitted that Applicants' specification provides more than sufficient disclosure to objectively enable one of ordinary skill in the art to make and use the claimed compounds. Therefore, withdrawal of the rejection of claims 1-33 under 35 USC §112, first paragraph, is respectfully requested.

Rejection Under 35 USC §103

Claims 1-33 are rejected under 35 USC §103(a) in view of WO 99/32437. It is recognized in the Office Action that the reference does not disclose the substituent required on "L" as defined in claim 1 (SO₂R_x, COR_x or C(NR_y)R_z). It is alleged that "one of skill in the art would have been motivated to make a substitution similar to a nitro or amino group such as CN(R_y)R_z and COR_y which differs by just one carbon atom".

Applicants maintain that the compounds of this invention are structurally unobvious over the compounds of WO 99/32457 such that a side by side comparison is not necessary.

No evidence has been presented to show nitro groups or amine groups are considered by

those skilled in the art to motivate use of the groups SO_2R_y , COR_y or $\text{CON}(\text{R})_x\text{R}_y$ in the claimed compounds. Contrary to the allegation made in the Office Action, the substituents described in WO 99/32437 are not structurally similar to those herein. These structures differ from nitro and amino groups by more than just one carbon atom as the examiner incorrectly alleges. There is clearly no motivation or direction to substitute the nitro or amino group of WO 99/32437 with the substituents of the claimed compounds. In the absence of such motivation, the rejection under 35 USC §103(a) is untenable. See *In re LaLu* (CAFC 1984) 747 F.2d 703, 223 USPQ 1257.

Based on the above remarks, Applicants submit that claims are in a condition suitable for allowance and patentable over the prior art. Therefore, withdrawal of the rejections and allowance of these claims are earnestly solicited. The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



Richard J. Traverso (Reg. No. 30,595)
Attorney/Agent for Applicant(s)

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

Attorney Docket No.: BAYER 15P3

Date: July 15, 2002

RJT/lvb:aeK

K:\Bayer\15P3\reply 7-15-02.dot